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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,484	01/23/2002	Keith Alan Foster	1581.0870000/RWE/MTT	2134

7590 06/21/2004

Sterne Kessler Goldstein & Fox
Suite 600
1100 New York Avenue NW
Washington, DC 20005-3934

EXAMINER	
AUDET, MAURY A	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 06/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,484	FOSTER ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-42* is/are pending in the application.

4a) Of the above claim(s) *30-38 and 43-47* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-42* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *9/26/01 & 4/18/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group III, claims 39-42, in the paper filed 02/27/2004 is acknowledged. The traversal is on the ground(s) that the Examiner misconstrued what the special technical feature (i.e. medicinal lectins), and that at least Groups IV-VI and X should be rejoined. This is not found persuasive because as stated in the Office Action of 1/29/04, at page 6, even if "a lectin is the special technical feature, a lectin alone does not run through every invention claimed . . . [t]hus, there is no special technical feature among Groups I-X and they lack unity". Therefore, a search more than Groups III would pose an undue burden.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II or III, restriction for examination purposes as indicated is proper.

The requirement is still deemed proper and is therefore made FINAL.

35 U.S.C.§ 112, 1st ¶, Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 39-42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the

application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is primarily drawn to use of an Erythrina cristagalli lectin (ECL) conjugate to modulate C-fibre activity in order to treat any disease or condition resulting from inhibition or stimulation of C-fibre activity.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention, namely treating any C-fibre neuron associated diseases/conditions (claim 39), nor the distinctly claimed conditions of psoriasis and mucus hypersecretion (claim 42), by an ECL conjugate. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, the specification has adequately described the use of ECL conjugates in a method of treating two (2) C-fibre associated diseases or conditions: pain (i.e. analgesic affect in mouse, See Figure 3 and Example 5 and 6) and inflammation (pretreatment stimulated rat paw, See Figure 13 and Example 18). There is no description as to how or whether an ECL conjugate would be able treat the other the other 2 specifically claimed C-fibre neuron diseases/conditions

(psoriasis and mucus hypersecretion) of claim 42 or any C-fibre neuron diseases/conditions as contemplated by claim 39. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of a method of treating any C-fibre neuron associated diseases/conditions; other than pain and inflammation, using an ECL conjugate.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed invention, namely any ECL "conjugate" for use in the method(s) of the present invention. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, the specification has adequately the conjugation of ECL to the clostridial enzyme designated LH_N/A (See Example 3). There is no description for any other compound conjugated to ECL, nor has any other ECL conjugate been tested for use in the methods of the present invention. One of skill in the art would not recognize from the disclosure that the Applicant was in possession of a method of treating any C-fibre neuron associated diseases/conditions; other than pain and inflammation, by any ECL conjugate, other than ECL- LH_N/A.

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. 112 is severable from its enablement provision (see page 1115).

35 U.S.C. § 112, 1st ¶ Scope of Enablement

Claims 39-42 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling (notwithstanding the straight Enablement Rejection) for a method of treating the C-fibre neuron associated diseases/conditions of pain and inflammation by an ECL conjugate (Figures 3 and 13), does not reasonably provide enablement for treatment of any C-fibre neuron associated diseases/conditions (claim 39), nor the distinctly claimed conditions of psoriasis and mucus hypersecretion (claim 42), by an ECL conjugate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

> The first paragraph of 35 U.S.C. 112 states, "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same...". The courts have interpreted this to mean that the specification must enable one skilled in the art to make and use the invention without undue experimentation. The courts have further interpreted undue experimentation as requiring "ingenuity beyond that to be expected of one of ordinary skill in the art" (Fields v. Conover, 170 USPQ 276 (CCPA 1971)) or requiring an extended period of experimentation in the absence of sufficient direction or guidance (In re Colianni, 195 USPQ 150 (CCPA 1977)). Additionally, the courts have determined that "... where a statement is, on its face, contrary to generally accepted scientific principles", a rejection for failure to teach how to make and/or use is proper (In re Marzocchi, 169 USPQ 367 (CCPA 1971). Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in In re Colianni, 195 USPQ 150, 153 (CCPA 1977), have been clarified by the Board of Patent Appeals and Interferences in Ex parte Forman, 230 USPQ 546 (BPAI 1986), and are summarized in In re Wands (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988). Among the factors are the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the amount of direction or guidance present, the presence or absence of working examples, the breadth of the claims, and the quantity of experimentation needed.

The instant disclosure fails to meet the enablement requirement for treatment of any C-fibre neuron associated diseases/conditions by an ECL conjugate for the following reasons:

The nature of the invention: The elected invention is drawn to the use of Erythrina cristagalli lectin (ECL) conjugate to modulate C-fibre activity in order to treat any disease or condition resulting from inhibition or stimulation of C-fibre activity.

The amount of direction or guidance present and the presence or absence of working examples: Enablement must be provided by the specification unless it is well known in the art. *In re Buchner* 18 USPQ 2d 1331 (Fed. Cir. 1991). A search of the prior art, as to ECL conjugates for treating C-fiber related disorders, revealed very limited number of teachings directed to the specific invention of the present application, therefore, the use of ECL conjugates for treating C-fiber related disorders cannot be construed as being well known in the art, and thus reliance for enablement must stem from the specification. The specification and claims have adequately described the use of ECL conjugates in a method of treating two (2) C-fibre associated diseases or conditions: pain (i.e. analgesic affect in mouse, See Figure 3) and inflammation (pretreatment stimulated rat paw, See Figure 13). There are no working examples to indicate whether ECL conjugates would be enabled for treating the other the other 2 specifically claimed C-fibre neuron diseases/conditions (psoriasis and mucus hypersecretion) of claim 42 or any C-fibre neuron diseases/conditions as contemplated by claim 39. One of skill in the art would not recognize from the disclosure that any C-fibre neuron associated diseases/conditions; other than pain and inflammation, was enabled in a method of treatment using an ECL conjugate.

The breadth of the claims and the quantity of experimentation needed: The claims are drawn broadly to the use of ECL conjugates in a method for treating any C-fibre neuron associated diseases/conditions. Absent sufficient teachings in the specification or art sufficient to overcome the teachings of unpredictability in the art as to enablement on whether any C-fibre neuron associated diseases/conditions may be treated using an ECL conjugate; it would require undue experimentation by one of skill in the art to be able to practice the invention commensurate in scope with the claims.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 39-42, it is unclear what the invention is. Namely, Applicant's elected invention is a method of treating a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity, by modulating C-fibre activity, comprising administering an effective amount of an Erythrina cristagalli lectin conjugate (claim 1); wherein said conjugate may inhibit (claim 40) or stimulate (claim 41) C-fibre activity. It is unclear how an Erythrina cristagalli lectin conjugate can both inhibit and stimulate C-fibre activity, in order to treat a disease or condition resulting from an inhibition or stimulation of C-fibre neuron activity? Applicant is asked to point out where in the specification support may be found for both types of modulation by an Erythrina

cristagalli lectin conjugate, or amend the claims to more distinctly claim the invention. Additionally, it is suggested that Applicant amend the claims to distinctly claim only the elected invention.

In claim 39-41, it is unclear what is meant by the term "modulating" C-fibre activity? Claim 40 and 41 describe inhibiting and stimulating C-fibre activity, but it is nevertheless unclear what is contemplated by the step of "modulating" C-fibre activity, in order to treat various C-fibre originating diseases or conditions.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached at 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA
6/8/04

CHRISTOPHER R. TATE
PRIMARY EXAMINER